UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,257	02/12/2004	Joachim Koerner	5000.P0019US	5395

23474 7590 07/11/2011

FLYNN THIEL BOUTELL & TANIS, P.C.
2026 RAMBLING ROAD
KALAMAZOO, MI 49008-1631

EXAMINER	
PATEL, NIHIR B	

ART UNIT	PAPER NUMBER
3772	

MAIL DATE	DELIVERY MODE
07/11/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JOACHIM KOERNER, MICHAEL HELMLINGER,
HOLGER SCHUERLE and RENE BOMMER

Appeal 2010-002715
Application 10/777,257
Technology Center 3700

Before RICHARD M. LEBOVITZ, STEPHEN C. SIU, and
DANIEL S. SONG, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 by the Patent Applicant from the Patent Examiner's rejections of claims 10-19. The Board's jurisdiction for this appeal is under 35 U.S.C. § 6(b). We affirm-in-part.

STATEMENT OF THE CASE

The claims are directed to methods of operating a microdosing device. According to Application Serial No. 10/777,257 (hereinafter "the '257 application"), which is the application involved in this appeal, the device can be used to precisely dose liquids, such as pharmaceutical agents ('257 application, ¶¶ [005] & [006]). The device comprises a vibrating unit, such as a piezoelectric actuator, which vibrates the liquid so that it is atomized through the discharge opening in the dosing chamber of the device (*id.* at ¶ [002]). After discharge from the device, the atomized liquid is inhaled by a patient. The device also comprises a "drying function," to free the dosing chamber of liquid residue after atomization (*id.* at ¶ [005]).

Claims 10-19 stand rejected by the Examiner as follows:

Claims 10-19 under 35 U.S.C. § 102(b) as anticipated by Hess[1] (Ans. 4-5); and

Claim 10 under 35 U.S.C. § 112, first paragraph, as lacking written description (*id.* at 4).

Claims 10, 12, and 14 are representative and read as follows:

> 10. A method of operating a micro dosing device having a dosing chamber for the at least partial reception of a liquid quantity and with which is associated at least one discharge opening, a vibrating unit in operative connection with at least one boundary surface of the dosing chamber in order to

[1] U.S. Patent No. 6,196,219 B1 issued Mar. 6, 2001.

vibrate the same for a discharge process, a delivery function unit, connected to the vibrating unit, for activating the latter during a delivery time period, and a drying function unit, the method comprising the steps of:

activating the vibrating unit during a delivery time period;

pausing for a pre-determined time separation period; and

activating the drying function unit to remove liquid residues from the dosing chamber.

12. A method of operating a microdosing device having a dosing chamber for the at least partial reception of a liquid quantity and with which is associated at least one discharge opening, a vibrating unit in operative connection with at least one boundary surface of the dosing chamber in order to vibrate the same for a discharge process, a delivery function unit, connected to the vibrating unit, for activating the latter during a delivery time period, and a drying function unit for removing liquid residues from the dosing chamber, configured for activation in time-separated manner with respect to the delivery function unit, wherein the delivery function unit and drying function unit are parts of a common electronic control device provided with a time function element for coordinating the time-separated activating processes of the delivery function unit and the drying function unit, the method comprising the steps of:

activating the delivery function unit to dispense a medium;

activating the time delay unit for a pre-determined time separation; and

activating the drying function unit for a drying process.

14. A method for dosing small liquid quantities by the vibration of at least one boundary surface of a dosing chamber by activating and deactivating a vibrating unit, comprising the steps of:

activating the vibrating unit for a delivery time period for the discharge of the liquid quantity,

> deactivating the vibrating unit and initiating a time delay; and
>
> initiating a drying process to remove liquid residues remaining in the dosing chamber.

ANTICIPATION BY HESS

Legal Principles

"[W]hile it is true that claims are to be interpreted *in light* of the specification and with a view to ascertaining the invention, it does not follow that limitations from the specification may be read into the claims." *Sjolund v. Musland*, 847 F.2d 1573, 1581 (Fed. Cir. 1988). "[L]imitations are not to be read into the claims from the specification." *In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993).

Findings of Fact ("FF")

[FF1] Hess describes:

> drug administration devices, and in particular . . . a device for administrating a drug to a patient by means of his or her respiratory system. Such an inhalation device, in its simplest form, is commonly called an inhaler. It may be used e.g. for the controlled administration of drugs or for a variety of therapies using aerosolised drug administration including anaesthetics. The inhaler delivers the drug, which is in the form of a liquid substance, as a dispersion of atomised droplets. Preferably, such a device is small in size and battery operated so that the patient may carry and use it in a discreet manner.

(Hess, col. 1, ll. 5-16.)

[FF2] Hess's device is acknowledged in the '257 application to correspond to the same basic structure of the microdosing device described in the '257 application ('257 application, ¶¶ [002] & [015]).

[FF3] To atomize the drug and discharge it from the device, Hess's device comprises a vibrating element:

> Device 5 preferably comprises a vibrating element 10, e.g. a piezoelectric element, attached to the exterior bottom surface of bottom substrate 8 in the vicinity of its thinner middle section to cause vibration of substance 4 in space 9 through the membrane part of substrate 8.

(Hess, col. 6, ll. 23-27.)

[FF4] The vibrating element produces droplets comprising a drug substance which are ejected from the device (*id.* at col. 6, ll. 49-61; Abstract).

[FF5] Hess's device can comprise a heating surface which "may contribute at the end of the atomisation cycle to evaporate any minute amount of liquid left in space 9, same as a continuation for a predetermined time of the actuating of the vibrating means after the inhalation cycle has ended." (*Id.* at col. 7, ll. 18-22.)

Claim 10

This rejection turns on the issue of whether the steps recited in claim 10 must be performed in the specific order recited in the claim. We therefore begin our analysis with claim interpretation because a claim must be properly interpreted before it is compared to the prior art.

Claim Interpretation

Claim 10 is directed to a method of operating a microdosing device. The device comprises:

- a dosing chamber with a discharge opening;

• a vibrating unit in operative connection with a boundary surface of the dosing chamber to vibrate it for the discharge process; and

• a delivery function unit "connected to the vibrating unit, for activating the latter during a delivery time period"; and

• a drying function unit.

The method comprises three steps, recited in the following order:

• "activating the vibrating unit during a delivery time period;"

• "pausing for a pre-determined time separation period;" and

• "activating the drying function unit to remove liquid residues from the dosing chamber."

The claim recites "pausing for a pre-determined time separation period," but does not expressly specify between what steps the "pausing" is accomplished. The "pausing step" is recited after "activating the vibrating unit" and before "activating the drying function," but we discern no language in the claim that requires this specific order to be carried out.

> [A]lthough a method claim necessarily recites the steps of the method in a particular order, as a general rule the claim is not limited to performance of the steps in the order recited, unless the claim explicitly or implicitly requires a specific order. *See Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1342-43 (Fed. Cir. 2001).

Baldwin Graphic Sys., Inc. v. Siebert, Inc., 512 F3d 1338, 1345 (Fed. Cir. 2008).

Absent clear claim language, we do not interpret the claim to require that the "pausing" occur between activating the vibrating unit and activating the drying function. Although such an order of steps is described in one embodiment of the '257 application (¶ [008]), limitations from embodiments

described in the specification are not ordinarily read into the claims. *Sjolund,* 847 F.2d at 1581; *Van Geuns*, 988 F.2d at 1184.

Moreover, the claim does not recite a structure associated with the pausing step or with the time-separation period that would require them to occur between the recited activating steps. Because no structure is recited, the claim also does not limit how the pausing or pre-determined time-separation period is accomplished – for instance, manually or using specific structural elements. The '257 application describes a "time function element" (¶¶ [008] & [020]), but this element is not recited in claim 10 and therefore is not part of the claim.

In sum, there is no basis in the claim language for construing the claimed method to be limited to the specific order of steps recited in the claim.

Discussion

The Examiner found that all the steps of the claimed method were accomplished by Hess who described a device acknowledged to be the same device which is claimed (FF2). Appellants contend:

> [Hess] does not teach any pause between the inhalation and drying cycles, and the existence of a pause cannot be inferred from the absence of any disclosure related to the switching from the inhalation to the drying cycles. . . . [Hess] does not teach a method of operation of the microdosing device including a step of pausing for a pre-determined time separation period between a delivery time period and activation of the drying function unit to remove liquid residues from the dosing chamber, as required by Claim 10.

(App. Br. 7.)

The claims, when properly interpreted, are not limited to a "pause" between the inhalation delivery time period ("activating the vibrating unit") and the drying cycle ("activating the drying function unit"). While such order of steps may have been described in one embodiment of the '257 application, the claim language at issue does not limit the claim to only this order. Rather, the claims are more broadly interpreted to encompass performing the claim steps in a different order than recited in the claim. By statute, the *claims* must "particularly point[ ] out and distinctly claim[ ] the subject matter which the applicant regards as his invention." 35 U.S.C. § 112, second paragraph (2006). For this reason, we do not to read limitations from the Specification into the claims, absent express claim language or a definition in the application requiring us to do so.

Hess's device can be used more than once (FF1). The time between each use would constitute "pausing" for a time separation period, meeting the disputed limitation of the claim. Consequently, we affirm the rejection of claim 10, and dependent claim 11, which was not separately argued.

Claim 12

Claim 12 is directed to a method of operating a microdosing device with substantially the same elements as recited in claim 10. Claim 12 comprises activating the delivery function unit (first recited step), "activating the time delay unit for a pre-determined time separation" (second recited step), and activating the drying function unit (third recited step).

Appellants contend that Hess does not describe activating a time-delay unit as required by Claim 12 (App. Br. 8).

Claim 12 requires a "time function element" that coordinates time-separation between activating the claimed delivery (first step) and drying functions (third step). This element is characterized in the claim as follows (emphases added):

> a drying function unit for removing liquid residues from the dosing chamber, configured for activation in time-separated manner with respect to the delivery function unit, wherein the delivery function unit and drying function unit are parts of *a common electronic control device provided with a time function element for coordinating the time-separated activating processes of the delivery function unit and the drying function unit.*

A "time function element" is a specific structure in the claim that links the delivery function to the drying function steps (see italicized portion of claim 12 quoted above). The claim therefore would be reasonably understood, based on the claim language, to require a specific order of steps, where the time-separation step occurs between the delivery and drying steps.

The Examiner did not provide sufficient evidence that Hess described a "time function element" as recited in the claim nor that Hess described a time-separation for a pre-determined amount of time between the delivery and drying. Hess describes using a vibration element for delivery of drug substance from the dosing chamber (FF3 & FF4) and a heating surface to dry the dosing chamber (FF5), but Hess does not disclose a structure ("time function element"), as in claim 12, for producing "time-separated activating processes of the delivery function unit and the drying function unit." Because this structure is missing from Hess, Hess does not describe all the elements of claim 12 and therefore does not anticipate the claimed subject under 35 U.S.C. § 102. The rejection of claim 12, and dependent claim 13, is reversed.

Claim 14

Claim Interpretation

Claim 14 recites three steps in the following order:

• "activating the vibrating unit for a delivery time period for the discharge of the liquid quantity,"

• "deactivating the vibrating unit and initiating a time delay," and

• "initiating a drying process to remove liquid residues remaining in the dosing chamber."

As with claim 10, we do not interpret claim 14 to require that the steps be performed in the recited order. *See Baldwin*, 512 F3d at 1345.

Persons of ordinary skill in the art would have reasonably understood the recited "deactivating the vibrating unit" step to occur after the "activating the vibrating unit" step because it is logical that the vibrating unit would be turned off and de-activated only after it had been turned on and activated. However, there is no language or structure in the claim that would require deactivation to *immediately* follow the activation step. Rather, the deactivating and time delay could also after the step of "initiating a dry process."

Additionally, there is no structure in the claim associated with the recited "time delay." Thus, as with claim 10, the time delay could be accomplished manually or using specific, but unrecited structural elements.

The third recited step of initiating a drying process involves "remov[ing] liquid remaining in the dosing chamber." Liquid must therefore be present in the dosing chamber prior to this step. Liquid would pass into the loading chamber in order for it to be discharged. This would be understood to occur when the vibrating unit was activated "for a delivery

time period" as in the first recited step of the claim. Persons of ordinary skill in the art would thus reasonably interpret the drying process to occur after the vibrating unit has discharged liquid. However, such step could occur in any order after the activating step has taken; thus, it could be the second or third step of the claimed method.

Discussion

The issue in this rejection is whether Hess describes the step in claim 14 of "deactivating the vibrating unit and initiating a time delay." It is true, as Appellant argued, that Hess does not necessarily describe a time delay *between* atomization of the drug (FF5) ("activating the vibrating unit for a delivery time period" as in claim 14) and a heating step ("initiating a drying process" as in claim 14) (Reply Br. 2-3). However, the claim is not limited to this sequence of steps. Rather, claim 14 encompasses deactivating the vibrating unit and performing the time delay as the last and third step in the claim. This step is met by Hess because Hess's device can be used more than once (FF1). The time between each use would constitute a "time delay," meeting the disputed limitation of the claim. As the Examiner found that the remaining limitations of the claim were met by Hess, we affirm the rejection for the reason set forth by the Examiner (Ans. 4-7).

WRITTEN DESCRIPTION REJECTION

Legal Principles

To satisfy the written description requirement, the inventor "must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*." *Vas-Cath, Inc. v.*

Mahurkar, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). In describing the claimed invention, there is no requirement that the wording be identical to that used in the specification as long as there is sufficient disclosure to show one of skill in the art that the inventor "invented what is claimed." *Union Oil Co. of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989, 997 (Fed. Cir. 2000). Thus, so long as a person "of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate written description requirement is met." *In re Alton*, 76 F.3d 1168, 1175 (Fed. Cir. 1996).

"Although [the inventor] does not have to describe exactly the subject matter claimed . . . the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989).

Discussion

The Examiner rejected claim 10 for lack of written description under 35 U.S.C. § 112, first paragraph, because the '257 application as filed did not disclose "pausing for a pre-determined time separation period."

> The examiner would like to point out that the appellant's specification does not mention "pause" and "pre-determined". The term "paused for a pre-determined time separation period" as stated in the claims implies that a control unit on the device sets a time frame in which there is a pause in the operation for a pre-determined time where as the term "time separated manner" as stated in the specification implies that there is no set time frame by the control unit . . . .

(Ans. 7.)

The term "pause" is not recited in the '257 application. However, the lack of literal support for the term does not mean that the written description is not satisfied. *Union Oil Co.*, 208 F.3d at 997; *Alton*, 76 F.3d at 1175. Rather, the issue is whether persons of ordinary skill in the art would have recognized that Appellants invented what is claimed. *Gosteli*, 872 F.2d at 1012.

Because "pause" is not defined in the '257 application, we adopt its ordinary and conventional meaning of "a temporary stop or rest" between two actions.[2] As shown below, the '257 application describes a time-separation period between the delivery and drying action. Persons of ordinary skill in the art would have reasonably understood that a time-separation is a "stop" or "rest" between the two actions – and thus a "pause."

> This problem is solved in that *additionally a drying function unit is provided, which is activatable in time-separated manner from the delivery function unit* in order to free the dosing chamber from liquid residues. *As a result of the time separation of the delivery function and the drying function* a clearly time-defined dosability of the corresponding liquid is ensured. As a result it is possible to keep preferably at the same level the dosing volume over the time interval of the delivery function, so that a highly precise dosing is possible.

('257 Application, ¶ [005]; emphases added.)

The '257 application also describes switching off the vibrating unit from a time t2 and t3 between delivery and drying, which would be understood to be a defined or pre-determined time-separation period as claimed. This is shown in Figure 2 of the application, and explained in paragraph 20, both of which are reproduced below:

---

[2] RANDOM HOUSE DICTIONARY 975 (College Ed. 1968).

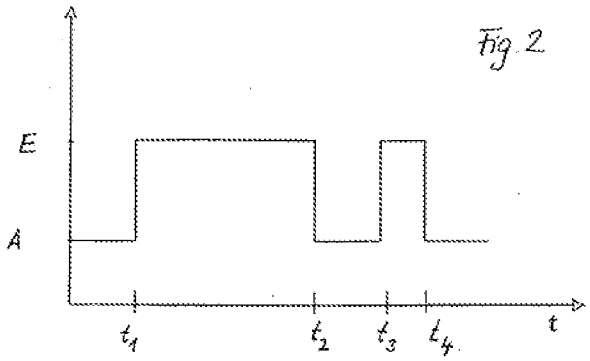

Figure 2, reproduced above, shows a block diagram of the function of the microdosing device. The '257 application explains:

> During the atomizing process in the time period t1 to t2 the microvalve 8 is opened by means of the actuating member 9. *As from the time t2 and up to a time t3 the piezoelectric actuator 6 is switched off*, i.e. deactivated. In order to remove any small liquid residues which may be present within the dosing chamber 3 before a corresponding liquid quantity is again supplied via the supply channel 7 and microvalve 8, *as from time t3 the piezoelectric actuator 6 is activated, i.e. switched on by the drying function unit 11.*

('257 Application, ¶ [020]; emphases added.)

As described above and illustrated in the drawing, there is a pre-determined period between t2 and t3 during which the vibrating is deactivated before the drying function is activated.

In view of the above-discussed disclosures, the evidence supports Appellants' argument that persons of ordinary skill in the art would have recognized that the inventors invented the claimed step of "pausing for a pre-determined time separation period." The rejection of claim 10 as lacking written description is reversed.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART

bim